1072000

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.

Address:

PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068

Contact:

Paul Biggins, Director Regulatory Affairs

Telephone No.:

(714) 730-5000

Device Proprietary Name: SSA-790A, Aplio XG Version 2.00

Common Name:

Diagnostic Ultrasound System

JUL 3 0 2007

Classification:

Regulatory Class:

Review Category:

Tier II

Ultrasonic Pulsed Doppler Imaging System - Product Code: 90-IYN

[Fed.Reg.No.:892.1550]

Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO

[Fed.Reg.No.:892.1560]

Diagnostic Ultrasonic Transducer – Product Code: 90-ITX

[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- 1) Toshiba SSA-790A, Aplio XG Version 1.00 Diagnostic Ultrasound; 510(k) control number k063130
- 2) Siemens Medical Solutions U.S.A. Acuson Sequoia Ultrasound System;510(k) control number k052410

Device Description:

The Aplio XG Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:

The Aplio XG is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL 3 0 2007

Toshiba America Systems, Inc % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K072000

Trade Name: Aplio XG Diagnostic Ultrasound System, Model SSA-790A version 2.0

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 20, 2007 Received: July 23, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio XG Diagnostic Ultrasound System, Model SSA-790A version 2.0, as described in your premarket notification:

Transducer Model Number

| PVT-375BT | <u>PLT-805AT</u> | <u>PST-50AT</u> |
|---------------|-------------------|-------------------|
| PVT661VT | <u>PLT-1204AT</u> | PST-65AT |
| PLT-1202S | <u>PLT-1204AX</u> | <u>PLT-704SBT</u> |
| <u>PC-20M</u> | <u>PVT-382BT</u> | <u>PLT-1204MV</u> |
| PET-510MB | <u>PVT-674BT</u> | PVT-382MV |
| PST-25BT | <u>PVT-575MV</u> | <u>PVT-681MV</u> |
| PLT-604AT | <u>PVT-770RT</u> | <u>PET-511BTM</u> |
| PLT-704AT | PST-30BT | |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

Page 2 – Mr. Job

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

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Enclosure(s)

| System X Transducer | |
|---------------------|--|
| Model SSA-790A | |
| 510(k) Number(s) | |

| | | Mode of Operation | | | | | | | | | | |
|----------------------------------|---|-------------------|---|------------------|----------|-----------------|--------------|----|----------|--|------------------------|-----------------------|
| Clinical Application | В | T,HI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | <u> </u> | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | P | | | P |
| Intraoperative (Specify) | P | P | P | P | P | | | P | | | | P |
| Intraoperative Neurological | | | | - | | | | | | | | <u> </u> |
| Pediatric | P | P | P | P | P | P | P | P | P | | | P |
| Small Organ (Specify)* | P | P | P | Ρ. | P | | · | P | <u> </u> | | | P |
| Neonatal Cephalic | P | P | P | P | P | P | 1 | P | P. | | | P |
| Adult Cephalic | P | P | P | P | P | Р | <u> </u> | P | P | | <u> </u> | P |
| Cardiac | P | P | P | P | P | P | P | P | P | P | | P |
| Transesophageal | P | P | P | P | | | P | P | P | | | Р |
| Transrectal | P | P | P | P | P | P | | P | | | | P |
| Transvaginal | P | P | Р | P | Р | P | | P | | | | P |
| Transurethral | | | | | | 1 | | | | | | |
| Intravascular | | | 1 | | | | | | | · | | |
| Peripheral Vascular | P | P | P | P | P | | | P | | | | P |
| Laparoscopic | | | | | <u> </u> | | 1 | | 1 | † | | <u> </u> |
| Musculo-skeletal Superficial | P | P | P | P | P | | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| 4.13 1 11 41 | | . 1 . 1000100 | |
|---------------------|-------------------------------|-----------------|--|
| All indication | ns were previously repor | ted via k063130 | |
| · For example: thur | oid, parathyroid, breast, scr | otum and nanis | |
| . 1 of example, my | old, paramyrold, breast, scr | otum and penis | |

Prescription Use (Per 21 CFR 801.109)11

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

| System Transducer X | • |
|---------------------|---|
| Model PVT-375BT | |
| 510(k) Number(s) | |
| | |

| · · · · · · · · · · · · · · · · · · · | Mode of Operation | | | | | | | | | | | |
|---------------------------------------|-------------------|----------|---|---------------------------------------|--|-----------------|--|----------|-------------|--|---------------------------------------|-----------------------|
| Clinical Application | В | тні | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | P | | P | | | | P |
| Abdominal | P | P | P | P | P | P | | P | | <u> </u> | | P |
| Intraoperative (Specify) | | | | | | | | | | \vdash | | |
| Intraoperative Neurological | | | | | | · · · · · · · · | | | | | | |
| Pediatric | P | P | P | P | P | P | | P | | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | - | <u> </u> | | | · <u>·</u> |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | <u> </u> | | | <u> </u> | · · · · · · · · · · · · · · · · · · · | |
| Transesophageal | | | | · · · · · · · · · · · · · · · · · · · | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | • | | | | _ | | | | |
| Transurethral | | | | | <u> </u> | | | | | | | |
| Intravascular | | | | *** | | | | | | | | |
| Peripheral Vascular | | l | | | | | _ | <u> </u> | | | | <u> </u> |
| Laparoscopic | | <u> </u> | | | | | - | | | | | |
| Musculo-skeletal Superficial | | | | | | | _ | | | | - | |
| Musculo-skeletal Conventional | | | | | | | | | | | | · |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: Combined Modes: B/M; B/BDF/PWD; BDF/MDF; BDF/MDF/PWD | /PWD; | |
|---|-------|-------------|
| 2211 T. D. DOTTMENT, BEST WILLTHIN W.D. | | |
| Previous 519(k) for this device k063130 | | |
| | | |

(PLRASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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Radiological Devices

| | <u> </u> | | | | | 3.5.1 | | | | | · | |
|---|--------------|-------------------|----------|-------------|----------------|-----------------|--|--------------------------|-----------------------------|--------------|-----------------|-----------|
| Clinical Application | В | тні | М | Color | Power | Mode Dynamic | of O | perati | On CW | СНІ | СНІ | Combined |
| | | | | Doppler | | Flow | | | | 2D | Dynamic Flow | (Specify) |
| Ophthalmic | Ī | | | | | | | | | | 1104 | |
| Fetal | | | | | | | | - | | | | |
| Abdominal | | | | | | | | | | · | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative | | | | | | | | | | | | |
| Neurological | | <u> </u> | | | ļ <u>.</u> | | <u> </u> | | | | | |
| Pediatric | <u> </u> | <u> </u> | 1 | | | | | | | | | |
| Small Organ (Specify)* | <u> </u> | ļ | | | | | | | | _ | | |
| Neonatal Cephalic | <u> </u> | ļ | | | | | | | | <u> </u> | | |
| Adult Cephalic | <u> </u> | ļ | - | | | | | | | | | |
| Cardiac | <u> </u> | ļ | 1 | | <u> </u> | | <u> </u> | | | | | |
| Fransesophageal | n | <u></u> | | | | | ļ | | | <u> </u> | | |
| Fransrectal | P | P | P | P | P | P | ļ | P | ļ | | ļ | P |
| Fransvaginal Fransurethral | r | l r | P | P | P | P | ļ | P | | | | P |
| ntravascular | ļ | | } | | - | | <u> </u> | <u> </u> | | | | |
| Peripheral Vascular | ├ | <u> </u> | 1 | | ļ | <u> </u> | | | | | | |
| Laparoscopic - | | ļ | | | | <u> </u> | | | ļ. <u> </u> | <u> </u> | ļ | |
| Musculo-skeletal | | | \vdash | | | | ļ | | ļ | ļ | <u> </u> | ···· |
| Superficial | · | | 1 | | Ì | 1 | | | | | | |
| Musculo-skeletal | ╁─ | - | \vdash | | | | ╂ | | | | | |
| Conventional | | | 1 | | | | | | | 1 | | |
| N= new indication Additional Comm BDF/PWD; BDF/ | ents MD | : F; <u>BD</u> | F/M | Combined | d Modes | : B/M; B/I | | under | Appe | ndix i | s(LIF) | |
| Prescription Use (| | Co | oncurr | ence of CDF | THIS LINE - C | Divis | sion S | (ODE) ign-Of Repro | √ <i>ov</i> f) ductiv | e, Abd | ominal and | 1 |

| System Transducer X | |
|---------------------|-------------------|
| Model PLT-1202S | |
| 510(k) Number(s) | |
| | |
| | |
| | Mada of Onesetton |

| | Mode of Operation | | | | | | | | | | | |
|----------------------------------|-------------------|-----|----|------------------|-------|-----------------|-----|----|----|-----------|------------------------|-----------------------|
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | - |
| Fetal | | | | | | | | | | , | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | P | P | P | P | P | | | P | | | | P |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | 1 | | | | |
| Small Organ (Specify)* | P | P | P | P | P | | | P | | | | P |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | ÷ | | | | | | | | |
| Transvaginal | | | 1. | | | | | | | | | |
| Transurethral | | | | | | | | | | 1 | | |
| Intravascular | 1 | | | , | | | | | | | | |
| Peripheral Vascular | P | .P | P | P | P | | | P | | | | P |
| Laparoscopic | | | T | | | | | 1 | 1 | | | |
| Musculo-skeletal Superficial | P | P | P | P | P | | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | | | P | | | | P |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: | Combined Modes: B/M; B/ | YPWD; |
|----------------------|---------------------------|---------------------------------------|
| BDF/PWD; BDF/MDF; BD | F/MDF/PWD | |
| | | |
| | | |
| Previous 510(k |) for this device k063130 | |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

| | Mode of Operation | | | | | | | | | | | |
|------------------------------------|-------------------|-------------|--------|------------------|--------------|-----------------|--|--------------|--------------|-----------|--|-----------------------|
| Clinical Application | В | тні | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | 1 | <u> </u> | | | | | | | | | Flow | |
| Fetal | | | | | | | | <u> </u> | | | | |
| Abdominal | | <u> </u> | | ···· | | | | | | | ··· | <u> </u> |
| Intraoperative (Specify) | | | | | 1 | | | <u> </u> | | | | |
| Intraoperative Neurological | | | | | | ~~ | | | | | • | |
| Pediatric | İ | | | | | | | | P | , , | | |
| Small Organ (Specify)* | | | | | | | | | - | | | |
| Neonatal Cephalic | | , | † † | | _ | | | | | | | |
| Adult Cephalic | | - | 1 | | | | | | | | | |
| Cardiac | | | | | | | | | P | | | |
| Transesophageal | | | | | | | - | | | | | |
| Transrectal | | | | | | | | | - | | | |
| Transvaginal | | | | | | | | - | | | | |
| Transurethral | | | | | <u> </u> | <u> </u> | i — | | | | | |
| Intravascular | | | 1 | | † | | | t | | | | |
| Peripheral Vascular | | - | † † | , | | | | | P | | | |
| Laparoscopic | | - | 1 1 | | | | - | | | | | |
| Musculo-skeletal | 1 - | | | | 1 | | <u> </u> | | | - | | |
| Superficial | | | | | : | | | | | | | |
| Musculo-skeletal | | | | | | | | | 1 | *····· | <u> </u> | |
| Conventional | | | | | | | | | | | | |
| N= new indication Additional Comm | | | viou | sly Cleare | ed by FE | OA; E = 2 | Added | unde | Appe | ndix E | E (LTF) | |
| | | - 5100 | | | | | | | | | | |
| P1 | eviou | S 210(k | tor th | iis device k0 | 63130 | · | | <u> </u> | | | - , - | |
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Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number ____

| Model <u>PET-5</u> 510(k) Number(| | <u>MR</u> | | | _ | | | | | | | |
|--------------------------------------|----------------|-------------------|---------------|---------------------------------------|------------------------------|--|--|--------------------|----------------|--------------|----------------|-----------------------|
| | | | | . | | ··· | | | | · | - | |
| | | Mode of Operation | | | | | | | | | | |
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dyпamie Flow | TDI | PW | cw | CHI 2D | CHI Dynamic | Combined (Specify) |
| Ophthalmic | ļ | | 1 | | | | - | | | | Flow | |
| Fetal | | | | | 1 | | | | | | | <u> </u> |
| Abdominal | | - "- | | | <u> </u> | | + | | | | | <u> </u> |
| Intraoperative (Specify) | | | | · · · · · · · · · · · · · · · · · · · | | | - | | · | | | |
| Intraoperative | | | | - | | | | 1 | | | | |
| Neurological | <u> </u> | <u></u> | | | | | | | | | | |
| Pediatric | | | | | | | | L | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | <u> </u> | <u> </u> | | | | | | | | | | - |
| Adult Cephalic | <u> </u> | | ļ | | | | | | | | | |
| Cardiac | <u> </u> | <u> </u> | | | <u> </u> | | | | | | | |
| Transesophageal | P | P | P | P | | | P | P | P | | | P |
| Transrectal | ├ | <u> </u> | | | | <u> </u> | ļ | <u> </u> | <u> </u> | | | |
| Transvaginal Transurethral | <u> </u> | | | | | | | ļ | | | | |
| Intravascular | | | | | | ļ | - | ļ <u>.</u> | ļ | | | |
| Peripheral Vascular | - | | - | | | | | ļ <u>.</u> | | | | |
| Laparoscopic | | | | | | | | <u> </u> | ļ <u> </u> | | | |
| Musculo-skeletal | ┼─ | | | . | | | <u> </u> | | ļ | | | |
| Superficial | | | | | | | | | | | | |
| Musculo-skeletal | | · · | | | - | | + | | | | | <u> </u> |
| Conventional | | | | | | | | | | | | |
| N= new indication | i: P | P = Pre | viou | sly Clear | d by FF |)A· F= | .l ∆∂ded | under | · Anno | ndiv D | (LTE) | |
| Additional Comm BDF/PWD; BDF/ | ents MD | : F; <u>BD</u> | F/MI | <u>Com</u> bined | l <u>Modes</u> B-TDI; | : B/M: B/ | PWD: | | | | | |
| | . (F | PLEASE D Co | O NOT | WRITE BELOW ence of CDR | THIS LINE - C H, Office (| CONTINUE ON CO of Device Eve | OTHER PAC aluation (| ES IF NEI (ODE) | EDED) | | | |
| Prescription Use (| Per 2 | 21 CF | R 80 | 1.109) | | Div Ra | vision o vision o diologio O(k) No | f Repi cal De | oduct vices | ive, Ab | dominal ar | 1 |

| System _ | Transducer X | | |
|----------|--------------|---|--|
| Model_ | PST-25BT | _ | |
| 510(k) N | umber(s) | | |
| | | | |

| | | | | | | Mode | of O | oerati | ou | • | | |
|----------------------------------|----------|-----|----------|------------------|-------|-----------------|----------|----------|----|-----------|------------------------|-----------------------|
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | P | P | P | Р | | | Р |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | P | P | P | P | P | P | P | P | P | | | P |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | | | P |
| Adult Cephalic | P | P | P | P | P | P | P | P | P | | | P |
| Cardiac | P | P | P | P | P | P | P | P | P | P | | P |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | 1 | | 1 | - | | 1 | - | |
| Transvaginal | | | | | | | 1 | | | | _ | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | 1 | | | | 1 | | | | | |
| Musculo-skeletal | | | T | | | | | | | | | |
| Superficial | <u> </u> | | <u> </u> | | | | <u> </u> | <u> </u> | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: _ | Combined Modes: B/M; B/PWD; | |
|------------------------|--|------------------|
| BDF/PWD; BDF/MDF; E | BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; | |
| CHI/2D; FEI/2D; CHI/B | DF; FEI/BDF | |
| | | |
| | | ··· <u>····-</u> |
| Previous 51 | 0(k) for this device k063130 | |
| | | |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

| | | | | | | Mode | of Or | erati | on | | | |
|---|--------|----------|----------|------------------|---------------|-----------------|----------|------------|-------|-----------|---|----------------------|
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combine (Specify) |
| Ophthalmic | | | | | | | | | | | Tiow | |
| etal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | - | |
| ntraoperative (Specify) | | | | | | | | | | | | |
| ntraoperative Veurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | P | P | P | P | P | P | | P | | | | P |
| Veonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | 1 | | | · |
| Cardiac | | | | | | | | | | | | |
| ransesophageal | | | | | | | | | | | | |
| ransrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | *************************************** | |
| Fransurethral | | | | | | | | | | | | |
| ntravascular | | | | | | | , | | | | | |
| Peripheral Vascular | P | P | P | P | P | P | | P | | | | P |
| _aparoscopic | | | | | | | | | | • | | |
| Musculo-skeletal Superficial | P | P | P | Р | P | P | | P | | | | P |
| Musculo-skeletal Conventional | P | P | P | P | P | P | | P | | | | P |
| N= new indication | ı; F | P = Pro | viou | sly Clear | ed by FD |)A; E= | Added | under | Арре | ndix I | E (LTF) | · · |
| Additional Comm BDF/PWD; BDF/ | | | | | d Modes | : B/M; B/I | PWD; | | ··- | | | · |
| | | | | | | | | | | | | |
| P | revioi | ıs 510(k |) for tl | nis device k0 | 63130 | | | | | | | |
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Division of Reproductive, Abdominal and

Radiological Devices

| System Transducer _X ModelPLT-704AT 510(k) Number(s) | | | | |
|--|------|----------|-------|------------|
| | Mode | of Opera | ation | _ T |

| | | Mode of Operation | | | | | | | | | | |
|----------------------------------|---|-------------------|---|------------------|-------|-----------------|-----|----|----|-----------|------------------------|-----------------------|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | , | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | E | E | E | E | E | E | | E | | | | Ε. |
| Neonatal Cephalic | | | | | | | | | | 1 | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | <u> </u> | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | 1 | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | Ē | E | E | E | E | E | | E | | 1 | | E |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | E | E | E | E | E | E | | E | | | | Е |
| Musculo-skeletal Conventional | E | Е | E | E | E | E | | E | | | | E |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: | Combined Modes: B/M; B/PWD; | | |
|----------------------|-----------------------------|---|--|
| BDF/PWD; BDF/MDF; BD | | | |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801,109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number __

| System Transducer X | |
|---------------------|--|
| Model PLT-805AT | |
| 510(k) Number(s) | |
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| | |

| | Mode of Operation | | | | | | | | | | | | |
|----------------------------------|-------------------|-----|-----|------------------|-------|-----------------|-----|----|----|-----------|-------------------------|-----------------------|--|
| Clinical Application | В | тні | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI. Dynamic Flow | Combined (Specify) | |
| Ophthalmic | <u> </u> | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | - | |
| Abdominal | | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | | |
| Pediatric | | | | | - | | | | , | | | | |
| Small Organ (Specify)* | E | E | E | E | E | E | | E | | | | E | |
| Neonatal Cephalic | | | | | | | | | | | | | |
| Adult Cephalic | | | | | | 1 | | | | | | | |
| Cardiac | | | 1 - | | | - | | | | | | | |
| Transesophageal | T | | | | | | | 1 | | | | | |
| Transrectal | | | | | | | | | | 1 | | | |
| Transvaginal | | | | | | | 1 | | 1 | | | | |
| Transurethral | | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | | |
| Peripheral Vascular | E | E | E | E | E | E | | E | | | | E | |
| Laparoscopic | | | | | | | | | | | | | |
| Musculo-skeletal Superficial | E | E | E | Е | E | E | | E | | | | E | |
| Musculo-skeletal Conventional | E | Е | E | E | E | E | | E | | | | E | |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: | Combined Modes: B/M; B/PWD; | L | |
|-----------------------|-----------------------------|---|--|
| BDF/PWD; BDF/MDF; BDI | F/MDF/PWD | | |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

| System Transducer X | |
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| Model PLT-1204AT | |
| 510(k) Number(s) | |
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| | ļ | | | | | Mode | of O | perati | on | | | |
|----------------------------------|---|-----|----|------------------|---------------------------------------|-----------------|------|--------|----|-----------|------------------------|-----------------------|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | 11 | | - 1 - 11 - 11 | | | | | <u> </u> | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | E | E | E | E | E | E | | Ē | | | | E |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | 1 | | | 1 | | |
| Transurethral | | | | | | | | | 1 | | | |
| Intravascular | 1 | | | | · · · · · · · · · · · · · · · · · · · | | | - | | 1 | | |
| Peripheral Vascular | E | E | E | E | E | E | | E | | 1 | | E |
| Laparoscopic | | | | | | | ļ | | ľ | 1 | | |
| Musculo-skeletal Superficial | E | E | Е | Ē | E | E | | E | | | | E |
| Musculo-skeletal Conventional | Е | E | E | Е | E | E | | E | | | | E |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: | Combined Mode | <u>s</u> : B/M; B/PWD; | | |
|-----------------------|----------------|------------------------|-------------|-------------|
| BDF/PWD; BDF/MDF; BDF | F/MDF/PWD | | | |
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

| 510(k) Number(s | 5) | | | | | | | | | | | |
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| | | | | | | | | | | | | |
| | | · · · · · · · · · · · · · · · · · · · | | | 1 | Mode | of O | perati | on | | | |
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | 1 | | | | | *** |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | : | | | | | | | *** | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | E | E | E | E | E | E | - | E | | - : | | E |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | † · | | | | | | | | | | · · · · · · · · · · · · · · · · · · · | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | - | | | | | | | | |
| Transrectal | <u> </u> | | | | *************************************** | | | | | | | |
| Transvaginal | 1 | | | | | | - | | | | | 1 |
| Transurethral | | | | | | | 1 | | | | | |
| Intravascular | | | | ! | | | 1 | | | | | |
| Peripheral Vascular | E | E | E | E | E | E | · · · · · · | E | | | | E |
| Laparoscopic | | | | | | | | | 1 | - | | |
| Musculo-skeletal Superficial | E | Е | E | E | E | E | | Е | | | | E |
| Musculo-skeletal Conventional | E | Е | E | E | E | E | | E | | | | E |

Additional Comments: Combined Modes: B/M; B/PWD;
BDF/PWD; BDF/MDF; BDF/MDF/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

| | | | | | | Mode | of O | nerati | ion | | | |
|---------------------------------|--------------|----------|--------------|------------------|-----------|-----------------|--|--------------------|--|--|----------------|-----------------------|
| Clinical Application | В | THI | M. | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic | Combined (Specify) |
| Ophthalmic | | - | 1 | | | <u> </u> | | | <u> </u> | | Flow | |
| Fetal | E | E | E | E | E | E | | E | | | | E |
| Abdominal | E | E | E | E | E | E | | E | | | | E |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative | | | | | | | | | | | | |
| Neurological | | | | • | | | | | | | | |
| Pediatric | E | E | E | E | E | Ē | | Е | | | | E |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | <u> </u> | | | | | | · | | | |
| Transrectal | ļ | | | | | | | | <u> </u> | | | |
| Transvaginal | | | | | <u> </u> | | | | | | | |
| Transurethral | | <u> </u> | | | | | | | <u> </u> | 1 | <u> </u> | |
| Intravascular | | | | | | | | | <u> </u> | | | <u> </u> |
| Peripheral Vascular | | | J., | | | | | | | | | |
| Laparoscopic | | ļ | <u> </u> | | <u> </u> | | ļ | | | | <u> </u> | |
| Musculo-skeletal | | | | | | | | | | | , | |
| Superficial Musculo-skeletal | | | 1 | | | | | - | + | | _ | - |
| Conventional | | | | ļ · | | | ļ | | | | | |
| N= new indication | |) - D- | | olv. Class | ad hat Dr | <u> </u> | | | <u> </u> | | C (LTC) | |
| Additional Comm BDF/PWD; BDF | | | | | | : B/M; B/ | PWD; | | | | | |
| Prescription Use | | | Concur | rence of CD | | Divi | aluation | (ODE) Sign-Of Repr | M Off) oducti | ve, Ab | dominal an | d \ |

| Clinical Application Ophthalmic Fetal Abdominal Intraoperative (Specify) Intraoperative | В | ТНІ | М | C 1 | | | | | | | | |
|--|----------|----------|----------|-------------------|---------------|-------------------------------|-----------|------------|---------------------------------------|-----------|------------------------|-----------------------|
| Fetal Abdominal Intraoperative (Specify) Intraoperative | | | | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Abdominal Intraoperative (Specify) Intraoperative | | | | | | | | ····· | · · · · · · · · · · · · · · · · · · · | | 1100 | |
| Intraoperative (Specify) Intraoperative | E | E | E | E | E | E | | E | | | | E |
| Intraoperative | E | E | E | E | E | E | | E | | | | E |
| | | <u> </u> | | | <u> </u> | | | | | | | |
| Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | *** |
| Small Organ (Specify)* | | | | | | | | [| | 1. | | |
| Neonatal Cephalic | | | | • | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | <u> </u> | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | <u> </u> | ļ | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | <u> </u> | | | |
| Laparoscopic | | ļ | | | ļ | | <u> </u> | | <u> </u> | <u></u> | | |
| Musculo-skeletal | | | | | | ļ | | | | | | |
| Superficial | ļ | ļ | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | } | | | | | | | 1 |
| N= new indication | | <u> </u> | <u> </u> | 1 01 | 11 777 | | | | <u> </u> | 11. | | |
| Additional Comm BDF/PWD; BDF/ | | | DF/M | Combine DF/PWD | d Modes | : B/M; B/ | PWD; | | | | | |
| | | | | | | | | | | | | |
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| | | | | | | Mode | of O | perati | on | | | |
|----------------------------------|--------------|-----|---------------------------------------|------------------|---------|-----------------|--|--|--------------|----------------|--|-----------------------|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | - | | | | | | | riow | |
| Fetal | E | E | E | E | E | E | \vdash | E | | | | Ė |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | • |
| Intraoperative | 1 | | | | | | | <u> </u> | | | | |
| Neurological | | ļ | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | - | | |
| Neonatal Cephalic | | | · · · · · · · · · · · · · · · · · · · | | | | | | | | | |
| Adult Cephalic | | | | ٠ | 1 | | | | | | | |
| Cardiac | | | | 7.00 | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | 1 | | | 1 | | 1 | | | | ·- | |
| Transvaginal | | | | | | | | 'l''''' | | | | |
| Transurethral | 1- | | | | | | | · · | | 1 | <u> </u> | |
| Intravascular | | | 1 | | 1 | | | | | - | | |
| Peripheral Vascular | | - | | | 1 | | | † · · · · · | | | | |
| Laparoscopic | <u> </u> | 1 | | | | | 1 | | | | | |
| Musculo-skeletal | | | | | | | | | | | | |
| Superficial | | | | | | | | | | | | |
| Musculo-skeletal |] | | | | | | | | | | | |
| Conventional | <u> </u> | | | | | | | | | | 1 | |
| Additional Comm BDF/PWD; BDF/ | | | | | d Modes | ; B/M; B/I | PWD; | | | | | |
| Prescription Use (| | C | oncuri | rence of CDI | | CONTINUE ON CO | | | EDĖD) | | | |

| | | | | | | Mode | of O | perat | ion | · · · · | · | <u>. </u> |
|--------------------------------|----------|---------------|-------|-----------------------------|--|----------------------------|--|--|--|--|-----------------|--|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic. | Combined (Specify) |
| Ophthalmic | | | | | | | - | | | | Flow | |
| Fetal | | | | | | | | | | · | | |
| Abdominal | | <u> </u> | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | 1 | | 1 | | | | | | | |
| Small Organ (Specify)* | | | | - | 1 | <u> </u> | | | <u> </u> | | | |
| Neonatal Cephalic | ļ | T | П | | | | 1 | | | - | | |
| Adult Cephalic | | | | | 1 | | <u> </u> | | 1 | | ļ <u>.</u> | |
| Cardiac | | | İ | | <u> </u> | *- | | | | | | |
| Transesophageal | | | | | 1 | | <u> </u> | | | | | |
| Transrectal | E | E | E | E | E | E | | E | | | | E |
| Transvaginal | | | | | | | | | | | | <u></u> |
| Transurethral | | | | | 1 | | | | | | | |
| Intravascular | | | | | | <u> </u> | 1 | | | | | |
| Peripheral Vascular | | | 1 | | 1 | - | | | <u> </u> | | | - |
| Laparoscopic | | 1 | | | T | | 1 | | | | | |
| Musculo-skeletal | | | | | | | | 1 | | <u> </u> | <u> </u> | |
| Superficial | | | | | | L. | | | | | | |
| Musculo-skeletal | | | | | | | | | | | | *** |
| Conventional N= new indication | | | | | | | | | | | | |
| Additional Comm BDF/PWD; BDF/ | | | | | d Modes | : B/M; B/ | PWD; | | | | | · |
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| 510(k) Number(| s) — | | | | | | | | | | | |
|---|-------------|-------|-----|---|--|-----------------|--------|--------|--|-----------|---------------------------------------|-----------------------|
| | | | | | | Mode | of O | perati | ion | | | <u></u> |
| Clinical Application | В | тні | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
|)phthalmic | | | | | | - | | | | | | - |
| etal | Ī | | | - · · · · - · · · · · · · · · · · · · · | | | | | | | | |
| bdominal | E | E | E | E | E | E | Е | E | E | | | E |
| ntraoperative (Specify) | | | | | | | | | | | | |
| ntraoperative Jeurological | 7 | | | | | | | | | , | | |
| ediatric | E | E | E | E | E | E | E | E | E | | | _ : |
| mall Organ (Specify)* | | | | , | | | | | <u> </u> | | | |
| leonatal Cephalic | E | E | E | E | E | E | E | E | E | | | E |
| dult Cephalic | E | E | E | E | E | E | E | Е | E | | | E |
| Cardiac | E | E | E | E | E | E | E | E | E | E | | E |
| ransesophageal | | | | | | ···· | - | | | | | |
| ransrectal | | | | | | | | | | | | |
| ransvaginal | | | | | ĺ | | | | | | | · |
| ransurethral | | | | | | | | | | | | |
| ntravascular | | | | | | | | | | | | |
| eripheral Vascular | | | | **** | <u> </u> | | | | 1 | | | |
| aparoscopic | | | | | | | | | | <u> </u> | | |
| ſusculo-skeletal | | | 1 | | | | | | - | | | |
| uperficial | | l. | | | | | | | | | | |
| Iusculo-skeletal | | | | | | | | | | | · · · · · · · · · · · · · · · · · · · | |
| Conventional | <u> </u> | | | | | | | | | | | |
| N= new indication Additional Comm BDF/PWD; BDF/ | ents | : | ı | Combined | d Modes | : B/M; B/F | PWD; | | | | E (LTF) | |
| BDF/PWD: BDF/ | MD | r: BD | H/M | OF/PWD: | R-TDI- | м.:ттт 21 | コルベコスズ | 13. DT | \F/C\X | /D- | | |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number

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| | T | | | | | | · | | | | <u> </u> | |
| | - | т | · · · · · · · | | т | Mode | of O | perati | on | | , | , |
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | 110W | |
| Fetal | | | 1 | | 1 | | | | | | | <u> </u> |
| Abdominal | | | | | | | | | ļ | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | E | E | E | E | | | E | Е | E | | | E |
| Small Organ (Specify)* | | | | | | | 1 | | t | <u> </u> | | |
| Neonatal Cephalic | E | E | E | Е | | | E | E | E | <u> </u> | | E |
| Adult Cephalic | | | | | | | | <u> </u> | 1 | | | |
| Cardiac | E | E | E | E, | | <u> </u> | E | E | E | | | E |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | 1 | | *** |
| Transvaginal | | <u> </u> | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | <u> </u> | | ļ | | | | | | | | | |
| Peripheral Vascular | | <u> </u> | | | | | | | | | | |
| Laparoscopic | <u> </u> | ļ | | | | | | | | | | |
| Musculo-skeletal | | | | | | | | | | | | |
| Superficial | ļ | <u> </u> | ļl | | | | | | ļ | ļ | | |
| Musculo-skeletal Conventional | | | | | į | | | | | | | |
| N= new indication | | | ال | | | | | <u></u> | <u> </u> | <u> </u> | | |
| Additional Comm BDF/PWD; BDF/ | ents/MD | : F; BD | F/M | Combine DF/PWD | d Modes ;B-TDI; | : B/M; B/I M-TDI; 2 | PWD; D/CW | D; BC | PF/CW | 'D; | | |
| Prescription Use (| | C | oncurr | ence of CDF | THIS LINE - C | 'n | atuation | (ODE) n Sign | Off) | ctive, | Abdominal | and |

| 510(k) Number(s | 8) | | | | | | | | | | | |
|--|--------------|-------------|-------------|-------------------|---------|----------------------------|-------------|--------|-------|-----------|---------------------------------------|-----------------------|
| | | * | | | | | | | | | | |
| | | | | | | Mode | of O | perati | ion | | · · · · · · · · · · · · · · · · · · · | |
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | - |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | · | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | E | E | E | E | | | E | E | E | | | E |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | E | E | E | E | | | E | E | E | | | E |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | E | E | E | E | | | E | E | Е | E | | E |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | <u></u> | | | | | | | |
| Musculo-skeletal | | - | | | | | | | | | | |
| Superficial | | <u> </u> | ļ | | | | 1 | ļ | | ļ | | |
| Musculo-skeletal | | | | | ļ | | | | | | | |
| Conventional N= new indication | <u> </u> | <u> </u> | | | 1 | | | | | <u> </u> | 1 | |
| Additional Comm BDF/PWD; BDF/ CHI/2D; FEI/2D | ents | :: F; BD | F/M | Combine DF/PWD | d Modes | : B/M; B/ | PWD; | | | | | |
| | (| | | | | CONTINUE ON CONTINUE ON CO | | | EDED) | | | |
| Prescription Use (| (Per | 21 CF | FR 80 | 01.109) | | (0 | Division | Sign- | Off) | ation A | Abdominal | and base |

Radiological Devices 510(k) Number

| | | | | · · · · · · · · · · · · · · · · · · · | | Mode | of O | perati | on | | | |
|--|----------------|-------|--------------|---------------------------------------|-------|------------------------|------|--------|--------------|--------------|------------------------|-----------------------|
| Clinical Application | В | ТНІ | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | - | ····- | | | | | | | | | FIOW | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | 1 | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | ļ | - | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | | N | | | | N |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | <u> </u> | | | | | | | | | | | |
| Cardiac | | | <u>.</u> | | | | | | | | | |
| Fransesophageal | | |] | | | | | | | | | |
| Fransrectal | | | | | | | | | | | | |
| Fransvaginal | | | | | | | | | | | | |
| Fransurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | N | N | N | N | N | N | | N | | | | N |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal Superficial | N | N | N | N | N | N | | N | | | | · N |
| Musculo-skeletal Conventional | N | N | N | N | N | N | | N | | | | N |
| N= new indicatio Additional Comm BDF/PWD; BDF | ients | i: | | Combine | | DA; E = S: B/M; B/I | | l unde | r Appe | endix I | E (LTF) | |

A-23

(Division Sign-Off)

Radiological Devices 510(k) Number

Division of Reproductive, Abdominal and

| System Transducer <u>X</u> |
|----------------------------|
| Model PLT-1204MV |
| 510(k) Number(s) |
| |

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|----------------------------------|-------------------|-----|---|------------------|-------|-----------------|-----|--|----|-----------|------------------------|-----------------------|
| | В | тні | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | | **** |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | , |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | N | N | N | N | N | N | | N | | | | N |
| Neonatal Cephalic | [| | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | | |
| Transurethral | 1 | | | | | | | ······································ | 1 | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | N | N | N | N | N | N | | N | 1 | | | N |
| Laparoscopic | | | | | 1 | | | | | | | |
| Musculo-skeletal Superficial | N | N | N | N | N | N | | N | | | | N |
| Musculo-skeletal Conventional | N | N | Z | N | N | N | | N | | | | N |

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

| Additional Comments: | Combined Mo | odes: B/M; B/PW | D; | |
|----------------------|-------------|-----------------|----|------|
| BDF/PWD; BDF/MDF; BI | DF/MDF/PWD | | | |
| | | | | |
| · | | | | |
| | | | | |
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| | | | | |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

| | Mode of Operation | | | | | | | | | | | | |
|--|-------------------|--|----------------|------------------|-------------|-----------------|--------------|----------------|--------------|--|------------------------|---------------------|--|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combine (Specify | |
| Ophthalmic | | | | | <u> </u> | | | | | | 1104 | | |
| Fetal | N | N | N | N | N | N | | N | | | | N | |
| Abdominal | N | N | N | N | N | N | <u> </u> | N | | | | N | |
| intraoperative (Specify) | - | | | | | | | | | | | | |
| Intraoperative | | | | | | | | | | | | | |
| Neurological Pediatric | N | N | N | N | N | N | | N | | | | N | |
| | | | 11 | 11 | 13 | 17 | ļ | IN | | - | | IN | |
| Small Organ (Specify)* Neonatal Cephalic | | | | | | | | - | ļ | ļ . <u></u> | | | |
| Adult Cephalic | | | + | | - | | ļ | ļ | - | | | | |
| Cardiac | | | - | • • | | | | | | <u> </u> | | | |
| | - | - | ļ | | - | | | | <u> </u> | | | ļ | |
| Fransesophageal Fransrectal | | | - | | | - | <u> </u> | <u> </u> | | | | | |
| | | | - | | | | <u> </u> | | | ļ | <u> </u> | ļ | |
| Fransvaginal | | <u> </u> | | | | | | 1 | ļ | | | - | |
| ransurethral | - | | | | - | | - | ļ - | | | | | |
| ntravascular | | - | | | - | | 1 | | | | | ļ <u>.</u> | |
| Peripheral Vascular | | | _ | | <u> </u> | <u> </u> | | ļ | | ļ | <u> </u> | | |
| aparoscopic | - | <u> </u> | - | | | ļ | ļ | ļ | ļ | | | ļ | |
| Musculo-skeletal Superficial | | | : | | | | | | | | | <u> </u> | |
| Musculo-skeletal | | | | | | | | | | | | | |
| Conventional N= new indication | | ļ. <u>. </u> | <u> </u> | | <u> </u> | | | | | | | | |

Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number

Prescription Use (Per 21 CFR 801.109)

| | | | | | | Mode | of O | perati | ion | | | |
|--------------------------|--|--------------|---------------|-------------------|-----------------|-----------------|--|--------------|--|--------------|---------------------------------------|---------------------|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combine (Specify |
| Ophthalmic | | | | | | - , | | l | | | riow | |
| Fetal | | | | | | | | | - | | · · · · · · · · · · · · · · · · · · · | |
| Abdominal | Ì | | 1 1 | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | - | | |
| Intraoperative | ļ | | + | | | | | | | | | |
| Neurological | | | | |] | | | | | | | |
| Pediatric | <u> </u> | <u> </u> | | | | | | | | ···· | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | † - | | † | | | <u> </u> | | | | |
| Adult Cephalic | ļ | | | | | | | <u> </u> | | - | | |
| Cardiac | - | | 1 | | | | \ | | | - | | |
| Transesophageal | - | | | | | | | | | | | |
| Transrectal | N | N | N | N | N | N · | | N | | | | N |
| Transvaginal | N | N | N | N | N | N N | | N | | | | N |
| Transurethral | - | | | | | | _ | <u> </u> | | | | |
| Intravascular | - | | | | | | - | | - | ļ | | - |
| Peripheral Vascular | | | | <u>.</u> <u>.</u> | <u> </u> | <u> </u> | | - | | | | |
| Laparoscopic | | <u> </u> | - | | | <u> </u> | | | ļ | | | |
| Musculo-skeletal | | | 1 | | | | | ļ | | | | |
| Superficial | | | | | | | | | | | | |
| Musculo-skeletal | | | | | | | + - | | | ļ | | ļ |
| Conventional | | | | | | | | | | | | } |
| N= new indication | 1; F | P = Pre | Viou | sly Clear | ed by FF | A· F= |) Added | under | r Anne | ndiv F | (I TE) | <u> </u> |
| | -, - | | | order. | od by 1 L | ,, <u>,</u> | ruucu | unuci | тррс | AIUIX I | z (LII') | |
| Additional Comm | ente | | | Combine | l Modec | · P/M· P/ | יכונעם. | | | | | |
| BDF/PWD; BDF/ | | | TO A | Combine | <u> 1 Modes</u> | : B/M; B/ | <u>PWD;</u> | | | | | • |
| Additional Comm | ents | : | | Combine | | : B/M; B/ | | . undo | rippo | AIGIA I | · (DIT) | |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

| | Mode of Operation | | | | | | | | | | | |
|---|--|-----------|----------|------------------|--------------|-----------------|--|-------------|----|--------------|---------------------------------------|-----------------------|
| Clinical Application | В | THI | М | Color Doppler | Power | Dynamic Flow | TDI | PW | CW | CHI 2D | CHI Dynamic Flow | Combined (Specify) |
| Ophthalmic | | | | | | | | | | | FIOW | |
| Fetal | | | 1 | | | | | | | | | - |
| Abdominal | | | | | | | | | | | | |
| Intraoperative (Specify) | | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify)* | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Cardiac | | | | | | | | | | | | |
| Transesophageal | N | N | N | N | | ` | N | N | N | | | N |
| Transrectal | | | | | | | | | | | | · |
| Transvaginal | | | | | | | | - | | | | |
| Transurethral | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Musculo-skeletal | 1 | | | | | | | | | | | |
| Superficial | ļ | | | | | | ļ | | | | | |
| Musculo-skeletal | | | | | | | | | 1 | | | |
| Conventional | ــــــــــــــــــــــــــــــــــــــ | <u> </u> | <u> </u> | | | | | <u> </u> | | | | |
| N= new indication Additional Comm BDF/PWD; BDF/ | ents | : <u></u> | • | Combine | d Modes | : B/M; B/I | PWD; | | | | | |
| | | | | - | | ; | | · · · · · · | | | | |
| | · | | | | , | | · - | | | | · · · · · · · · · · · · · · · · · · · | |
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| | | | | | | | | | | | | |

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices 510(k) Number